

### **DETAILED ACTION**

This Office Action is in response to Applicants' Amendment and Remarks filed on 12 February 2010 in which claims 30, 32 and 34 are amended to change the scope and breadth of the claims, and new claims 60-62 are added.

The Declaration of Mr. Masahiro Kubota (not an inventor), submitted by Applicants on 18 February 2010 under 37 CFR § 1.132, is acknowledged and will be further discussed below.

Claims 30, 32, 34 and 60-62 are pending in the instant application and are examined on its merits herein.

### ***Priority***

This application is a National Stage entry of PCT/JP05/03234 filed on 21 February 2005 and claims priority to Japan foreign application 2004-043481 filed on 19 February 2004. A certified copy of the foreign priority document in Japanese has been received. An English translation of the foreign priority document and a statement certifying the accuracy of the translation was received on 23 October 2009. Thus, Applicants' have perfected their claim to foreign priority.

The following prior art rejections of record in the previous Office Action are maintained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Section [0001]**

Claims 30, 32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by PG Pub No. US 2002/0037291 A1 to Kawahara *et al.* (of record).

Kawahara *et al.* disclose glycosphingolipids that exhibit moisturizing and immuno-enhancing activity. The glycosphingolipids are extracted from the *Sphingomonas* sp. and have the structures as set forth in formula (I) (paragraphs 013-0018). The glycosphingolipids typically exhibit moisturizing effect and and immuno-enhancing activity, which allow them to be used for cosmetic and pharmaceutical compositions (paragraph 0035). The cosmetic or pharmaceutical composition containing the glycosphingolipid can be in any form, such as a solid, liquid, paste, jelly or powder (paragraph 0036). The cosmetic or pharmaceutical composition can be used in toilet soaps, face washes, rinses, eye creams, sunscreen lotions, suntan creams, hair washes, lip creams, etc. (paragraph 0037). Although not explicitly indicated, since Kawahara *et al.* disclose that the compounds are useful as a cosmetic or pharmaceutical composition, and further discloses the use of the glycosphingolipid in different compositions, it is the Office's position that this compound is intended for

Art Unit: 1623

administration to a mammal. The courts have stated that "when considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005).

It is furthermore noted that the Kawahara '704 patent does not explicitly disclose that the glycosphingolipid activates NKT cells, IL-4 production, or IFN- $\gamma$  production. However, whether the glycosphingolipid activates NKT cells, IL-4 production, or IFN- $\gamma$  production or not, is considered a mere mechanism of action of the glycosphingolipid. The recitations "activating NKT cells," "accelerating IL-4 production," and "accelerating IFN- $\gamma$  production," in the claim is considered to be merely a mechanism of the action of the application. Applicants' recitation of a new mechanism of action for the prior art method would not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Note that a mechanism of action of a treatment would not by itself carry patentable weight if the prior art teaches the same or nearly the same method steps.

Thus, the disclosure of glycosphingolipids extracted from the *Sphingomonas* sp. and their use as a cosmetic or pharmaceutical composition necessarily meets the instant claim limitations.

**Section [0002]**

Claims 30, 32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,348,201 B1 to Murata *et al.* (hereinafter referred to as the '201 patent; of record).

The Murata '201 patent discloses external compositions for the skin comprising glycosphingolipids extracted from the *Sphingomonas* sp. (column 2, lines 26-37). The compositions have potent moisturizing and skin roughness preventive effects (column 2, lines 12-15). The glycosphingolipids have the structures as setforth in formula (I) (column 2, line 38 – column 3, line 67). The external composition for the skin is available as toilet soaps, eye creams, sun-screening lotions, suntan creams, ointment, medicated lip cream, etc. (column 4, lines 1-13). The Murata '201 patent further discloses application of the external composition to the skin, hair or fingernails (claim 23). Although not explicitly indicated, since the Murata '201 patent discloses that the compositions are applied to the skin, hair or fingernails, it is the Office's position that this compound is intended for administration to a mammal. The courts have stated that "when considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005).

It is furthermore noted that the Murata '201 patent does not explicitly disclose that the glycosphingolipid activates NKT cells, IL-4 production, or IFN- $\gamma$  production. However, whether the glycosphingolipid activates NKT cells, IL-4 production, or IFN- $\gamma$  production or not, is considered a mere mechanism of action of the glycosphingolipid.

Art Unit: 1623

The recitations “activating NKT cells,” “accelerating IL-4 production,” and “accelerating IFN- $\gamma$  production,” in the claim is considered to be merely a mechanism of the action of the application. Applicants’ recitation of a new mechanism of action for the prior art method would not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Note that a mechanism of action of a treatment would not by itself carry patentable weight if the prior art teaches the same or nearly the same method steps.

Thus, the disclosure of glycosphingolipids extracted from the *Sphingomonas* sp. and their use as an external composition for the skin necessarily meets the instant claim limitations.

#### *Response to Arguments*

Applicants’ arguments, filed 12 February 2010, with respect to the rejection of claims 30, 32 and 34 made under 35 USC § 102(b) as being separately anticipated by PG Pub No. US 2002/0037291 A1 to Kawahara *et al.* and U.S. Patent No. 6,348,201 B1 to Murata *et al.*, and the Declaration of Mr. Masahiro Kubota (not an inventor), submitted by Applicants on 18 February 2010 under 37 CFR § 1.132, have been fully considered but they are not persuasive.

Applicants argue, and further submit a Declaration by Mr. Kubota to support their arguments, that the cited references are silent with respect to activation of NKT cells, IL-4 production, and IFN- $\gamma$  production, and there is no disclosure or suggestion in the references that the methods disclosed therein would result in these effects. In an effort

Art Unit: 1623

to further distinguish the claimed invention from that of the prior art, Applicants argue that the cited references only contemplate external uses involving topical application of GSL to the skin for completely different purposes, which is in contrast to the instant claims which contemplate administering GSL internally. This argument is not persuasive because the feature upon which Applicants relies (i.e., internal administration as compared to topical administration in the art) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants also argue that the rejection based on inherency of activation of NKT cells, IL-4 production, and IFN- $\gamma$  production is based on pure speculation because there is not the remotest implication in either of the applied references that GSL activates NKT cells, IL-4 production, or IFN- $\gamma$  production, regardless of whether GSL is administered externally for topical use or internally, such as by injection. Applicants further argue that not all GSLs have the same mechanism of action, nor is there a reasonable certainty that topical applications of GSL produces the same effects as recited in the instant claims. These arguments are not persuasive because while it may not be necessarily the case that all GSLs have the same mechanism of action, the GSLs disclosed in the prior art encompasses the compounds used in the method of the instant claims. As the compounds are the same, they would necessarily induce the same mechanism of action. Furthermore, the active step in Applicants' claimed method is "administering to a mammal a cell activator comprising a glycosphingolipid having a

Art Unit: 1623

structure represented by the following formula (3).” As further clarified in the instant claim amendments, the preamble of the claim, “activating NKT cells,” “accelerating IL-4 production,” and “accelerating IFN- $\gamma$  production,” would result upon practicing the active method step. Thus, as Kawahara *et al.* and the Murata ‘201 patent each separately teach the use of a composition comprising a GSL, as encompassed by the instant claims, in a cosmetic composition for topical application, also encompassed by the instant claim limitations, the mechanism of “activating NKT cells,” “accelerating IL-4 production,” or “accelerating IFN- $\gamma$  production,” would necessarily result upon topical application of the disclosed composition comprising GSL to the skin. Moreover, assuming *arguendo* that Applicants’ argument is valid, which it is the Examiner’s position that it is not, Applicants’ arguments suggest that the full scope of the instant claims, which encompasses topical administration, are not enabled. As Applicants repeatedly argue that “the claimed invention contemplates administering GSL internally to accomplish...activating NKT cells...accelerating IL-4 production, and accelerating IFN- $\gamma$  production,” it is respectfully requested that Applicants amend their claims to be commensurate in scope with their contemplated invention.

Therefore, the Declaration of Mr. Masahiro Kubota is ineffective to rebut the *prima facie* case presented herein.

The rejection is still deemed proper and therefore maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Section [0003]**

Claims 30, 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,672,693 to Kawahara (hereinafter referred to as the '693 patent; of record), as evidenced by journal publication by Laloux *et al.* (of record), in view of journal publication by Nicoara *et al.* (of record).

The Kawahara '693 patent discloses glycosphingolipids isolated from the *Sphingomonas* sp. The compounds are denoted as GSL-1, GSL-2, GSL-3, and GSL-4 and their structures are shown in columns 3-6. The Kawahara '693 patent teaches that the glycosphingolipid compounds exhibit a B cell activating effect and a differentiation-deriving effect on animal cells, as determined from their cell mitogenic activity in spleen cells prepared from the spleen of 7 week old mice (column 11, lines 16-32). Thus, the Kawahara '693 patent states that the glycosphingolipids are expected to be useful as an immunoactivator (column 7, lines 55-59).

It is noted that the Kawahara '693 patent does not explicitly disclose that the immunoactivator activates NKT cells, IL-4 production, or IFN- $\gamma$  production. However, how the glycosphingolipid immunoactivators act is considered a mere mechanism of action of the glycosphingolipid immunoactivators. Applicants' recitation of a new mechanism of action for the prior art method would not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. In the instant case, the prior art reference teaches that the compound is an immunoactivator, but does not explicitly teach what part of the immune system it is activating. However, as evidenced by Laloux *et al.*, NKT cells are present in mice spleen, which also produces IFN- $\gamma$  and IL-4 upon activation. Furthermore, Applicants are requested to note

Art Unit: 1623

that a mechanism of action of a treatment would not by itself carry patentable weight if the prior art teaches the same or nearly the same method steps.

The teachings of the Kawahara '693 patent differ from the instantly claimed invention in that the Kawahara '693 patent does not teach administration of the glycosphingolipids to a mammal.

Nicoara *et al.* teach that immunomodulators have been used to stimulate the defense mechanisms for treatment of viral, bacterial, parasitic and fungal diseases (p. 303, column 2, last paragraph). Furthermore, the field of clinical immunomodulation further holds promise in the treatment of immunodeficiency diseases, infections, and cancers (p. 304, column 1, first incomplete paragraph).

As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the Kawahara '693 patent, concerning the use of glycosphingolipids from the *Sphingomonas* sp. as immunoactivators, with the teachings of Nicoara *et al.*, regarding the use of immunomodulators to stimulate the defense mechanisms for treatment of viral, bacterial, parasitic and fungal diseases. Since the Kawahara '693 patent teaches that the disclosed glycosphingolipids can be used as immunoactivators, and Nicoara *et al.* teach that immunomodulators are used to stimulate the defense mechanisms for treatment of viral, bacterial, parasitic and fungal diseases, one of ordinary skill in the art would have been motivated to use the glycosphingolipids disclosed in the Kawahara '693 patent as immunoactivators in the treatment of viral, bacterial, parasitic and fungal diseases with a reasonable expectation of success since the glycosphingolipids are taught to have the desired function for use

Art Unit: 1623

in the treatment of the said diseases. Furthermore, since the Kawahara '693 patent shows that the glycosphingolipids have cell mitogenic activity in spleen cells, Applicants are requested to note that the courts have found utility for therapeutic inventions despite the fact that an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition. See MPEP § 2107.01. Moreover, the Federal Circuit, in *Cross v. Iizuka*, 753 F.2d 1040, 1051, 224 USPQ 739, 747-48 (Fed. Cir. 1985), commented on the significance of data from *in vitro* testing that showed pharmacological activity by stating that “[w]e perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the compound in question. Successful *in vitro* testing will marshal resources and direct the expenditure of effort to further *in vivo* testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an *in vivo* utility.”

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

#### *Response to Arguments*

Applicants' arguments, filed 12 February 2010, with respect to the rejection of claims 30, 32 and 34 made under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,672,693 to Kawahara, as evidenced by journal publication by Laloux *et al.*, in view of journal publication by Nicoara *et al.*, and the Declaration of Mr. Masahiro

Art Unit: 1623

Kubota (not an inventor), submitted by Applicants on 18 February 2010 under 37 CFR § 1.132, have been fully considered but they are not persuasive.

Applicants argue, and further submit a Declaration by Mr. Kubota to support their arguments, that the Kawahara '693 patent discloses that their disclosed glycolipid possesses a B cell mitogen activity, which is different from the instant claims in which GSL works directly with CD1d. This argument is not persuasive because "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112 [R-3]. Moreover, this new property cannot be considered to be unexpected merely because it was not previously recognized in the prior art composition. In other words, since the combined teachings of the prior art disclose the active step of Applicants' claimed method, "administering to a mammal a cell activator comprising a glycosphingolipid having a structure represented by the following formula (3)," whether the prior art discloses the end result that NKT cells are activated, IL-4 production is accelerated, or IFN- $\gamma$  production is accelerated is inconsequential as the recited mechanism would necessarily result upon practicing the active method step of administering the GSL to a mammal. The patient population requiring treatment for viral, bacterial, parasitic and fungal diseases is deemed to

Art Unit: 1623

overlap with the patient population requiring activation of NKT cells, acceleration of IL-4 production, and acceleration of IFN- $\gamma$  production.

Applicants further argue that none of the cited prior art references teach *in vivo* administration of GSL to a mammal for any purpose. This argument is not persuasive because the Kawahara '693 patent expressly teaches that the disclosed the glycosphingolipids are expected to be useful as an immunoactivator and Nicoara *et al.* teach that immunomodulators have been used to stimulate the defense mechanisms for treatment of viral, bacterial, parasitic and fungal diseases. Thus, it would have been *prima facie* obvious to use the GSLs disclosed in the Kawahara '693 patent to treat viral, bacterial, parasitic and fungal diseases in a mammal, as the Kawahara '693 patent teaches that their disclosed GSLs are immunoactivators and Nicoara *et al.* teach that immunomodulators can be used to stimulate the defense mechanisms for the treatment of various diseases. While the Kawahara '693 patent only discloses *in vitro* testing of the GSLs, the teachings of Nicoara *et al.* would motivate one of ordinary skill in the art to apply the methods to an *in vivo* setting. Furthermore, Applicants are requested to note that the courts have found utility for therapeutic inventions despite the fact that an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition. See MPEP § 2107.01. Moreover, the Federal Circuit, in *Cross v. Iizuka*, 753 F.2d 1040, 1051, 224 USPQ 739, 747-48 (Fed. Cir. 1985), commented on the significance of data from *in vitro* testing that showed pharmacological activity by stating that “[w]e perceive no insurmountable difficulty, under appropriate circumstances, in

Art Unit: 1623

finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the compound in question. Successful *in vitro* testing will marshal resources and direct the expenditure of effort to further *in vivo* testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an *in vivo* utility.”

Therefore, the Declaration of Mr. Masahiro Kubota is ineffective to rebut the *prima facie* case presented herein.

The rejection is still deemed proper and therefore maintained.

The following are new ground(s) of prior art rejections necessitated by Applicants' amendment, filed on 12 February 2010, wherein dependent claims 60-62 are newly added.

#### **Section [0004]**

Claims 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,672,693 to Kawahara (hereinafter referred to as the '693 patent; of record), as evidenced by journal publication by Laloux *et al.* (of record), in view of journal publication by Nicoara *et al.* (of record), as applied to claims 30, 32 and 34, further in view of Goodman & Gilman's The Pharmacological Basis of Therapeutics (PTO-892, Ref. U), in view of PGPub No. US 2004/0127429 A1 to Tsuji (PTO-892, Ref. A).

The teachings of the Kawahara '693 patent, as evidenced by Laloux *et al.*, and the teachings of Nicoara *et al.* were as disclosed above in section [0003] of the claim rejections under 35 USC § 103.

The combined teachings of the Kawahara '693 patent, as evidenced by Laloux *et al.*, and the teachings of Nicoara *et al.* differ from that of the instantly claimed invention in that the combined teachings of the prior art do not disclose how the GSL is administered to a mammal for treatment of viral, bacterial, parasitic and fungal diseases.

Goodman & Gilman's teaches that drugs are commonly administered parenterally or orally. The route of administration takes into account the bioavailability of the drug (p. 5, column 1). Table 1-1 (p. 6) discusses some characteristics of the common routes of drug administration, including their advantages and limitations. Oral ingestion is typically the most convenient and economical method.

Tsui teaches synthetic C-glycolipids useful in treating cancer, infectious diseases and autoimmune diseases (paragraph 0003). GSLs, such as GalCer and their mimetics, activate NKT cells and cytokine production (paragraphs 0011-0012). Similar to their native counterparts, the disclosed compounds are also potent mediators of NKT cells (paragraph 0003). Moreover, compositions comprising the GSLs can be applied parenterally (paragraph 0123) or topically (paragraph 0124).

As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the Kawahara '693 patent, concerning the use of glycosphingolipids from the *Sphingomonas* sp. as immunoactivators, with the

Art Unit: 1623

teachings of Nicoara *et al.*, regarding the use of immunomodulators to stimulate the defense mechanisms for treatment of viral, bacterial, parasitic and fungal diseases, with the teachings of Goodman & Gilman's, regarding the different forms of drug administration, with the teachings of Tsuji, regarding the use of C-glycolipids for treating cancer, infectious diseases, and autoimmune diseases, similar to their native GSL counterparts. The various routes of drug administration are commonly known in the art, as discussed in Goodman & Gilman's. Thus, selecting the appropriate route of drug administration is considered to be within the capabilities of one of ordinary skill in the art. Furthermore, as Goodman & Gilman's teaches the advantages and limitations of the various routes of administration, it is considered that one of ordinary skill in the art would be able to best determine which route is most suitable for the patient, depending on such factors as severity of condition, age of patient, etc. Moreover, as Tsuji teach that GSLs having structures very similar to those encompassed by the instantly claimed methods can be administered parenterally or topically for treating cancer, infectious disease and autoimmune diseases, by activating NKT cells and cytokine production, one of ordinary skill in the art would have a reasonable expectation of success in administering the GSL compounds disclosed in the Kawahara '693 patent by parenteral, oral, or topical methods, for the treatment of cancer, viral, bacterial, parasitic and fungal diseases, which one would also reasonably expect to activate NKT cells and cytokine production. The patient population requiring treatment for viral, bacterial, parasitic and fungal diseases is deemed to overlap with the patient population requiring activation of

Art Unit: 1623

NKT cells, acceleration of IL-4 production, and acceleration of IFN- $\gamma$  production as Tsuji teaches that this mechanism is known to be induced by GSLs.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

The following obviousness-type double patenting rejection of record in the previous Office Action is maintained.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30, 32 and 34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S.

Patent No. 6,348,201 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to an external composition for the skin

Art Unit: 1623

comprising a sphingoglycolipid extracted from the bacterium *Sphingomonas*. Structures of the sphingoglycolipids are identified in claim 16. The external composition takes various forms, including as a medicated lip cream or anti-atopic agent. The patent further claims application of the external composition to the skin, hair, or fingernails.

The claims of the instant application are drawn to a method of activating NKT cells, IL-4 production, or IFN- $\gamma$  production, which comprises administering to a mammal a cell activator comprising a glycosphingolipid having the structure as shown in the instant claims.

Thus, the instant claims 30, 32 and 34 are seen to be anticipated by claims 1-23 of U.S. Patent No. 6,348,201 B1.

### *Response to Arguments*

Applicants' arguments, filed 12 February 2010, with respect to the rejection of claims 30, 32 and 34 made under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,348,201 B1, have been fully considered but they are not persuasive.

Applicants argue that the patent discloses only an external composition for topical application to the skin, and that it is silent with respect to activation of NKT cells, IL-4 production and IFN- $\gamma$  production. Applicants further argue that the instant claims are drawn to *in vivo* administration in order to activate of NKT cells, IL-4 production and IFN- $\gamma$  production. These arguments are not persuasive because the active step of Applicants' claimed method, "administering to a mammal a cell activator comprising a

Art Unit: 1623

glycosphingolipid having a structure represented by the following formula (3),” is anticipated by the patent which claims application of an external composition comprising sphingoglycolipid extracted from the bacterium *Sphingomonas* to the skin, hair, or fingernails. The sphingoglycolipids of the patent are the same as those used in the instantly claimed method. Thus, as the patent teaches the exact same method steps as that of the instant claims, whether the patent expressly indicates that the end result is activation of NKT, acceleration of IL-4 production, or acceleration of IFN- $\gamma$  production is inconsequential as the recited mechanism would necessarily result upon practicing the active method step of administering the GSL to a mammal. Moreover, the patient population requiring topical application of the aforementioned composition deemed to overlap with the patient population requiring activation of NKT cells, acceleration of IL-4 production, and acceleration of IFN- $\gamma$  production.

The rejection is still deemed proper and therefore maintained.

### **Conclusion**

In view of the rejections to the pending claims set forth above, no claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1623

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/SCARLETT GOON/  
Examiner  
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